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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,020	02/10/2004	Gregory B. Altshuler	105090-0234	2206
21125	7590	05/16/2006		
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER JOHNSON III, HENRY M	
			ART UNIT 3739	PAPER NUMBER

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,020

Applicant(s)

ALTSHULER ET AL.

Examiner

Henry M. Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 15, 16 and 18-26 is/are rejected.
- 7) ☐ Claim(s) 12, 14 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 020606.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 4/12/2006 have been fully considered but they are not persuasive. Applicant's arguments are directed to the removal of heat and motivation to combine. A skilled artisan in light therapy is most certainly cognizant of the heat generated by various sources of radiation and as such would look to known means for control of the heat. Chen et al. in the incorporated by reference U.S. Patent 5,445,608 discloses materials of construction to remove heat and to use the heat as part of the treatment process by directing the waste heat to tissue. The motivation to combine selected elements of devices with the common goal of enhancing oral hygiene is clearly not a huge leap to one skilled in the art.

Regarding drug delivery ports, the structure is for ports. The intended use of a fluid port is not significant in an apparatus claim.

Regarding the Obvious Double Patenting rejections (provisional), each of the applications clearly addresses removal of heat; 10/776686 in claim 26, 10/776687 in claim 24 and 10/777022 in claim 29.

Specification

Complete continuation data is required including the application number, filing data and status; i.e. Now abandoned, now Patent No. 6,648,904.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In*

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re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9-16, 18, 19 and 21-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6-9, 22-29, 32, 33 and 35-40 of copending Application No. 10/776686. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 6-16 and 18-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 9-23, 25-32 and 34-46 of copending Application No. 10/777022. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 6-16 and 22-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-9, 22-29 and 36-39 of copending Application No. 10/776687. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 10, 15, 16, 18, 19-22 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 98/06456 to Chen et al. Chen et al. teach an apparatus employing light therapy to treat oral conditions (abstract) including a mouthpiece that surrounds the teeth and gums (Fig. 2) that may be comfortably left inside a patient's mouth for extended times (page 2, lines 32-35) and is made from an elastomeric material such as silicone (page 5, line 8). This is interpreted as a compliant mouthpiece. The radiation source is disclosed as an LED, laser diode, gas discharge lamp or filament bulb (page 3, lines 30-32). The source may be mounted on the mouthpiece or located external to the mouthpiece with the radiation delivered via fiber optics. The means for delivery may include diffusing material (page 3, line 25). The optical fibers deliver the radiation in different directions (page 6, lines 13-15). Portions of the mouthpiece may be highly reflective (page 7, line 21). The sources mounted around the mouthpiece clearly radiate in different directions. Chen et al. incorporates by reference U.S. Patent 5,445,608 that teaches the use of either an internal or external array of light sources and allows use of LEDs or laser diodes operating at two or more wavelengths, and the ability to selectively activate the sources operating at a given wavelength or waveband as desired, so that the light at the different

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wavelengths or wavebands is provided to the treatment site either sequentially or simultaneously from the light sources (Col. 8, lines 37-45. The sources may be controlled by monitoring the temperature rise of the tissue (diagnostic sensor) (Col. 8, line 8). The current regulation will control the power of the light source. The '608 reference further teaches that waste heat produced by the array of LEDs or LDs disposed on the implantable probe can be employed to augment the PDT by increasing the temperature of the tissue at the treatment site (abstract) and the use of heat sinks (Fig. 1) for heat dissipation.

Regarding claim 8, the disclosure of a gas discharge source inherently produces a polychromatic radiation. Chen et al. teach specific wavelengths for treatment and therefore it is inherent that filters would be employed to obtain the desired wavelength when using a polychromatic source as one skilled in the art would surely remove wavelengths considered harmful.

Regarding claim 22, the light sources are capable of penetrating various tissues based on the power and time. Even low powers can produce significant fluences over time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent Application Publication US 2003/0113684 to Scott. Muller teaches a toothbrush with a head with bristles and a radiation source in a handle. The location in the handle is disclosed as convenient if the toothbrush is an electrical toothbrush, i.e. having electrical drive means to move the cleaning bristles in a tooth cleaning operation. The electric drive is interpreted as a vibrating mechanism. The radiation is directed in a direction parallel to the bristles either between the bristles or through the optically transparent bristles, thus teaching a plurality of emitters (Fig. 6). The bristles are interpreted as part of the total head and as optical elements and capable of radiating in multiple directions as they are deflected during brushing. A reflecting surface directs the radiation to the bristles (Fig. 6, # 17). Along with the radiation source in the handle, a detector is disclosed for sensing reflected radiation. This detector is interpreted as a diagnostic sensor (Col. 2, lines 38-65). The apparatus is clearly capable of radiating any area within an oral cavity. The radiation source may be a light emitting diode (LED) of known type and filters and mirrors are disclosed in the optical path. The bristles are interpreted as being capable of conforming to a portion of the oral cavity (teeth). Muller does not teach heat dissipation means. Heat generated by LEDs is well known to those with skill in the art. Scott teaches the use of heat sinks for dissipating heat generated by LEDs. It would have been obvious to one skilled in the art to use the heat sinks as taught by Scott in the handle of the invention of Muller to control the head of the radiating sources that are disclosed as being located in the handle. A skilled artisan would be motivated to look to the heat sink art for means to control or remove the heat of the light source.

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Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent Application Publication US 2003/0113684 to Scott as applied to claim 1 above and further in view of U.S. Patent 5,133,102 to Sakuma. Muller and Scott are discussed above, but do not teach a contact sensor. Sakuma discloses an electronic toothbrush with a handle, head and bristles and a circuit that energizes a radiation device when the bristles contact the teeth, thus sensing contact and completing the circuit via the body of the user. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the contact sensor as taught by Sakuma in the device of Muller/Scott to activate the device when in the preferred use position, in contact with the oral tissue to prevent extraneous radiation.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent Application Publication US 2003/0113684 to Scott as applied to claim 1 above and further in view of U.S. Patent 4,333,197 to Kuris. Muller and Scott are discussed above, but do not teach the use of ultrasonics. Kuris teaches an ultrasonic toothbrush with a handle, head and bristles driven by ultrasonic frequencies (abstract). The handle is designed to remove the heat produced by the ultrasonic generator (Col. 4, lines 28-31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the ultrasonic generator as taught by Kuris in the device of Muller/Scott to complement the hygienic process within an oral cavity as a skilled artisan would look to other devices in the art for guidance.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller in view of U.S. Patent Application Publication US 2003/0113684 to Scott as applied to claim 1 above and further in view of U.S. Patent 5,658,148 to Neuberger et al. Muller and Scott are discussed above, but do not teach the use of delivery ports. Neuberger et al.

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teach a dental brush with an optical fiber (Fig. 2, # 21) that carries radiation from a radiation source and water or liquid passage (Fig. 2, # 22) that carries water or liquid under pressure to the brushhead (Col. 3, lines 25-28). The port clearly cited and its intended use is not a patentable limitation in an apparatus claim. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an agent delivery means as taught by Neuberger et al. in the invention of Muller/Scott as drugs for use as photosensitizers are pervasive in the photodynamic therapy arts.

Allowable Subject Matter

Claim 12, 14 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

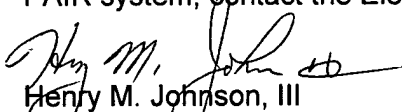
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Primary Examiner
Art Unit 3739